#### I. Provisions on Basic Labor Standards

#### A. Enforceable Obligation as to ILO Standards

Countries would be required to adopt, maintain and enforce in their own laws and in practice the five basic internationally-recognized labor standards, as stated in the 1998 ILO Declaration:

- 1. Freedom of association;
- 2. The effective recognition of the right to collective bargaining;
- 3. The elimination of all forms of forced or compulsory labor;
- 4. The effective abolition of child labor and a prohibition on the worst forms of child labor; and
- 5. The elimination of discrimination in respect of employment and occupation.

The obligations of this agreement, as they relate to the ILO, refer only to the 1998 ILO *Declaration on the Fundamental Principles and Rights at Work*.

#### B. Enforcement of Law

A decision a Party makes on the distribution of enforcement resources shall not be a reason for not complying with the provisions of this Chapter. Each Party retains the right to the reasonable exercise of discretion and to *bona fide* decisions with regard to the allocation of resources between labor enforcement activities among the internationally recognized labor rights, provided the exercise of such discretion and such decisions are not inconsistent with the obligations of this Chapter.

There would be a requirement to show that nonenforcement of law occurred "in a manner affecting trade or investment between the parties" and "through a sustained or recurring course of action or inaction."

## C. <u>Enforceable Non-Derogation Provision</u>

Parties cannot derogate from this obligation in a manner affecting trade or investment.

#### D. Full Parity in Dispute Settlement

Labor obligations subject to same dispute settlement, same enforcement mechanisms (remedies), and same criteria for selection of enforcement mechanisms (remedies) as all other FTA obligations.

## II. Provisions on Environment and Global Warming

## A. <u>Enforcement of Multilateral Environmental Agreements<sup>1</sup></u>

1. The Parties must adopt, implement, and effectively enforce laws, regulations and all other measures to fulfill the Parties' obligations under each of the following MEAs, to which they are both parties, subject to existing and future reservations to the MEAs:

Convention on International Trade in Endangered Species
Montreal Protocol on Ozone Depleting Substances
Convention on Marine Pollution
Inter-American Tropical Tuna Convention
Ramsar Convention on the Wetlands
International Convention for the Regulation of Whaling
Convention on Conservation of Antarctic Marine Living Resources

The MEAs listed include current and future mutually-agreed protocols, amendments, annexes, or adjustments to the listed MEAs to which the Parties have agreed.

- 2. The obligation in (1) is subject to the FTA dispute settlement chapter, and there shall be an inconsistency if the failure to uphold the obligation affects trade or investment.
- 3. The Parties may agree in writing to modify the list in (1) to include any other environmental or conservation agreement to which they are full parties.
- 4. In the event of any inconsistency between the FTA and the obligations set out in any MEA listed in (1) a Party shall seek to balance obligations under both agreements, but this shall not preclude a Party from taking a particular measure to comply with its MEA obligations, as long as the measure's primary purpose is not as a disguised restriction on trade. For greater certainty, this is without prejudice to non-covered MEAs.

#### B. Derogation

- (a) The FTA Parties cannot waive or otherwise derogate from, or offer to waive or otherwise derogate from, their respective environmental laws in a manner that weakens or reduces the protections afforded in those laws in a manner affecting trade or investment.
  - (b) A Party is in compliance with its obligations under (a) where such waiver or derogation is allowed under its environmental laws and such waiver or derogation is not inconsistent with a covered MEA.
- 2. Sub-paragraph (b) does not apply to waivers or derogations with respect to Peru's forest sector laws.

<sup>&</sup>lt;sup>1</sup> This obligation is in addition to the existing obligations to effectively enforce environmental laws, as defined in each agreement (see e.g., Peru Art. 18.2).

## C. <u>Dispute Settlement</u>

- 1. All FTA environmental obligations will be subject to same dispute settlement, same enforcement mechanisms (remedies), and same criteria for selection of enforcement mechanisms (remedies) as all other FTA obligations.
- 2. In applying the MEA obligation, dispute settlement panels convened under the FTA shall:
  - (a) follow (i.e., defer to) all interpretative guidance under the relevant MEA; and
  - (b) given all interpretative guidance, where an MEA obligation is open to more than one permissible interpretation, and an FTA Party has chosen one of those permissible interpretations, accept that interpretation as being in conformity with the MEA obligation. This specific guidance shall prevail over any other guidance.
- 3. FTA to establish mechanism for the FTA's Environmental Affairs Council (EAC) to coordinate interaction with the relevant MEA body on questions arising with respect to MEA obligations. The mechanism will establish procedures for the following:
  - (a) Where the EAC or an FTA panel considers matters related to adoption, implementation, or effective enforcement of laws, regulations and other measures necessary to fulfill obligations under a covered MEA, the EAC or FTA panel shall consult fully with the relevant MEA body(s).
  - (b) In such consultations, the EAC or FTA panel shall accept views of the relevant MEA body(s), including whether laws, regulations and other measures by an FTA Party are in accordance with the MEA.

4. FTA Parties shall endeavor to first address issues related to MEA obligations through mechanisms established in the relevant MEA. This shall not preclude an FTA Party from raising any matter related to MEA obligations through the EAC or from raising an alleged inconsistency with the obligation to adopt, implement and effectively enforce laws, regulations and all other measures to fulfill a covered MEA obligation, under the dispute settlement chapter, where recourse to the MEA mechanism could result in unreasonable delay, including where the MEA mechanism requires consensus.

## D. Logging (Peru)

- 1. USTR to conclude an Annex to the FTA covering forest sector governance and operations in Peru. Annex shall:
  - (a) Provide for coordination of capacity building activities in Peru under the Environmental Cooperation Agreement (ECA) [this can also be through an MOU];
  - (b) Provide for cooperation between the respective customs authorities and law enforcement authorities in regard to enforcement of forest sector laws;
  - © (I) Provide for steps strengthening Peru's forest sector laws, regulations and other measures in the areas of: (I) forestry sector governance; (II) concession management; (III) related trade activities; and (IV) regulation of harvesting, transport and export of CITES listed tree species:
    - (ii) Provide for a reasonable transition for Peru to implement the listed steps; and
    - (iii) Ensure that implementation of outlined steps is actionable and fully enforceable under the FTA dispute settlement chapter.
  - (d) Establish a fully enforceable obligation for Peru to conduct periodic audits of producers/exporters of CITES listed tree species (audits may be conducted by an agreed third party);
  - (e) Establish a fully enforceable right for the USG to request special audits and for verification procedures by U.S. Customs and the Fish and Wildlife Service for CITES listed tree species (audits may be conducted by an agreed third party);
  - (f) (i) Provide for restriction on U.S. imports of CITES tree listed species where Peruvian or U.S. verification shows that claim that the CITES listed species was legally harvested is insufficient or the producer/exporter provided incorrect information.
    - (ii) Provide for restriction on U.S. imports of CITES tree listed species from a given producer/exporter where request for verification denied or where producer/exporter knowingly provided false information. This provision is not intended to limit any existing or future authority under U.S. law for denying entry of shipments of CITES listed species or taking any other actions to enforce CITES.
- 2. Annex shall be developed by USTR, in consultation with State, the U.S. Forest Service, Fish and Wildlife, and Customs, and WM and Finance.

- 3. Specify that Peru forest sector laws are covered by definition of environmental laws.
- 4. Implementing legislation will provide for periodic Administration reports to Congress on relevant activities under the MOU, Annex, and ECA. SAA to list agencies that will be involved in developing the reports. The U.S. Forest Service, Fish and Wildlife Service, Customs, State, USTR and other appropriate agencies will participate in development of the reports.
- 5. Implementing legislation or other legislative vehicle (considered prior to the Peru implementing bill) to authorize and appropriate funds necessary for Customs and Fish and Wildlife to carry out responsibilities under the Annex, for capacity building money for Peru to implement obligations under the Annex, and to carry out activities of the ECA.
- 6. Make other changes to FTA text to make Annex workable. *E.g.*,
  - (a) Amend Peru Art. 18.2.3, which states that "nothing in this chapter shall be construed to empower a Party's authorities to undertake environmental law enforcement activities in the territory of the other Party." That provision should not apply to the verification procedures outlined above.
  - (b) Clarify that the Annex does not substitute for or amend Peru's obligations under CITES.

#### III. Provisions on Patents/IPR and Access to Medicines

#### A. Data Exclusivity

As a general rule, where a marketing approval application includes undisclosed test or other data, the FTA would provide for five years of data exclusivity for new chemical entities, taking account of the nature of the data and the person's efforts and expenditures in producing them. However, if a Party relies on marketing approval granted by the United States FDA, and if that Party grants approval within six months of an application for marketing approval by a person that produced the data, the five-year period begins when the drug was first approved in the United States (a so-called "concurrent period").

#### B. Patent Extensions

FTAs currently provide that a Party "shall" extend the term of a patent to compensate for any unreasonable delays in the patent or marketing approval process, provided the delay is not attributable to the applicant. "Shall" would be changed to "may" with respect to patents on pharmaceutical products.

FTAs would also provide that a Party shall make best efforts to process patent and marketing approval applications expeditiously with a view to avoiding unreasonable delays. The United States and the trading partner would agree to cooperate and provide assistance to one another to achieve these objectives.

## C. Linking Drug Approval to Patent Status

Amend FTA so that there is no "linkage" requirement between drug regulatory agencies and patent issues: in particular, no requirement that the drug regulatory agency withhold approval of a generic until it can certify that no patent would be violated if the generic were marketed.

However, a Party would be required to provide procedures and remedies, such as judicial or administrative proceedings and preliminary injunctions (or equivalently effective provisional measures), for adjudicating expeditiously any patent infringement or validity dispute that arises with respect to a product for which marketing approval is sought. There will be a transparent system to give patent holders sufficient time and opportunity to effectively enforce their rights (e.g., immediate notice sufficient to alert the

patent holder of submission of applications for marketing approval, such as the approval authority posting any application for marketing approval on its website, so that patent holders have opportunity to discover products that may infringe their patents), and to seek, prior to the grant of marketing approval, available remedies for an infringing product.

A Party could choose to implement the "procedures and remedies" obligation described above through a linkage system, provided that the Party makes available (1) an expeditious administrative or judicial procedure to challenge the validity or applicability of the patent (so as to break the "link" in appropriate cases), and (2) effective rewards for successfully challenging a patent. (U.S. law already meets this test.)

#### D. Side Letter on Public Health

The "Side Letter" currently included as part of U.S. FTAs should be made a part of the <u>text</u> of the FTA. The Parties (1) would affirm their commitment to the Doha Declaration, (2) clarify that the Chapter does not and should not prevent the Parties from taking measures to protect public health or from utilizing the TRIPS/health solution, and (3) include an exception to the data exclusivity obligation for measures to protect public health in accordance with the Doha Declaration and subsequent protocols for its implementation.

# E. Amendments to Chapter based on Economic Development

The FTA could include a provision calling for the periodic review of the implementation and operation of the IPR Chapter, and giving the Parties an opportunity to undertake further negotiations. The Parties could agree to consider, among other things, whether any improvement in the level of economic development in the territory of the other Party would support amendments to the chapter.

## **IV. Government Procurement**

Clarify that "technical specifications" requiring contractors to comply with generally applicable laws regarding fundamental principles and rights at work and acceptable conditions of work with respect to minimum wages, hours of work, and occupational safety and health, in the country in which the good is produced or the service is performed, do not create an "unnecessary obstacle to trade."

# V. Port Security

Clarify in services schedule that the specific commitment is subject to non-challengeable application of "essential security" exception to the FTA.

# VI. <u>Provision on Investment</u>

Include provision in Preamble to recognize that foreign investors in the United States will not be accorded greater substantive rights with respect to investment protections than United States investors in the United States.

## VII. Strategic Worker Assistance and Training (SWAT) Initiative

To promote education, training and portable health and pension benefits, design and implement concrete and comprehensive program, including public-private partnerships to educate youth, update and upgrade workers' skills on the job, stimulate science education and research, provide meaningful health and pension benefits and income support, go beyond the current TAA system to provide meaningful support, training and revitalization programs for entire communities hurt by the effects of trade and technology.

Note: there may also be private sector initiatives with respect to globalization and competitiveness.